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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,981	12/27/2001	Keith R. Edwards	NRI-001CN	1118

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 06/30/2005

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/034,981
Filing Date: December 27, 2001
Appellant(s): EDWARDS, KEITH R.

Debra J. Milasincic, Esq.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 06/21/04.

A handwritten signature, possibly "JL", in the bottom right corner of the page.

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(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

The amendment after final rejection filed on 11/19/2003 has not been entered.

(5) *Summary of Invention*

The summary of invention contained in the brief is deficient because the generic claim 1 does not recite "administering a bolus intravenous injection," rather an effective does of intravenous valproate is administered to a subject such that acute migraine headache is lessened or reduced.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

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(7) *Grouping of Claims*

The rejection of claims 1-14 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) *Claims Appealed*

A substantially correct copy of appealed claims 1-14 appears on pages 1 and 2 of the Appendix to the appellant's brief. The minor errors are as follows: The amendment after final was not entered and thus claim 1 should read (according to the amendment of 02/27/03) as follows: ---A method for the abortive treatment of acute migraine headache in a subject comprising administering to the subject an effective dose of intravenous valproate such that acute migraine headache is lessened or reduced in said subject---.

(9) *Prior Art of Record*

5,432,176

Walser

7-1995

Welch "Drug Therapy: Drug Therapy of Migraine" The New England Journal of Medicine, (Nov. 11, 1993), pp. 1476-1483

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-14 remain rejected under 35 U.S.C. 103(a). This rejection is set forth in a prior Office Action, mailed on 08/27/2002 and 05/19/2003.

(11) *Response to Argument*

On page 1476, Welch discloses that "the goals of migraine treatment are amelioration of the symptoms of an acute attack and prevention of further attacks" and on page 1479, right

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column and second full paragraph, Welch discusses that preventive treatment is considered when attacks of migraine occurs more than two or three times a month and such attacks are severe and limit normal activity to the extent that the patient is unable to cope. Welch in the third full paragraph of the right column of page 1479 also indicates that lowest dose is given at the outset. This discussion appears to imply the presence of migraine headache at the time preventative treatment is instituted. Also, Welch discusses that aspirin, acetaminophen, propoxyphen and codeine provide superior relief to placebo from pain of acute migraine (paragraph 5, left column, page 1476) and in the second full paragraph of page 1481, Welch further discloses valproate sodium is moderately effective in preventing migraine and reducing the frequency, severity and duration of severe attack as compared with placebo. Welch does not restrict when the valproate can and cannot be administered. Table 2 considers naproxen sodium, aspirin. Ketoprofen, tolfenamic acid, mefenamic acid and valproic acid as effective agents in the prevention of migraine. Since aspirin, naproxen sodium and valproate are classified as agents for preventing migraine (Table 2) and since also aspirin is stated in Welch to provide superior pain relief as compared to placebo, it follows that one of ordinary skill in the art would take valproate or aspirin when headache attacks. Walser discloses parenteral and oral modes of administering valproate, which is an agent that suppresses the production of glucocorticoid (column 4, lines 40-43; claims 1 and 3) and thus Walser discloses oral and parenteral modes of deliver as equivalent. Walser is relied solely for the parenteral mode of administration of valproate. The motivation is that parenteral mode of administration would get the valproate quicker to the blood stream. For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,




BF

June 18, 2005

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